UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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ANNIE TUMMINO, *et al.*,

Plaintiffs,

MEMORANDUM & ORDER

- against -

No. 12-CV-763 (ERK)(VVP)

MARGARET HAMBURG, Commissioner of Food and Drugs, *et al.*

Defendants.

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KORMAN, J.:

INTRODUCTION

I assume familiarity with the underlying facts and circumstances of this case that are detailed in my memorandum of April 5, 2013. *Tummino v. Hamburg*, --- F. Supp. 2d ----, 2013 WL 1348656 (E.D.N.Y. Apr. 5, 2013). Nevertheless, some introductory words are appropriate. This case involved Plan B and Plan B One-Step, emergency contraceptives that can be taken to reduce the risk of pregnancy after unprotected intercourse. They must, however, be taken as soon as possible after unprotected intercourse. The longer the delay, the less effective they become. The effort to convert these levonorgestrel-based contraceptives from prescription to over-the-counter status has gone on for over twelve years, even though they would be among the safest drugs available to children and adults on any drugstore shelf.

The FDA, responding to unjustified political interference, delayed as long as it possibly could before it took even one incremental step in the process. Ultimately, on December 7, 2011, in response to an application filed by Teva Women's Health ("Teva"), the FDA concluded that Plan B One-Step—the one-pill version of the drug—could be sold over-the-counter and without

a prescription or age restriction. The FDA was reversed by the Secretary of Health and Human Services on the same day in a decision that was politically motivated and that, even without regard to the Secretary's motives, was so unpersuasive as to call into question her good faith. Some five days later, the FDA rejected a Citizen Petition that sought unrestricted over-the-counter status for Plan B—the original two-pill emergency contraceptive product—and all drugs that are "equivalent" to Plan B. This decision was compelled by Secretary's reasoning in ordering the FDA to reject Teva's application. Specifically, the Secretary found that information that she deemed essential was not provided by Teva. The Citizen Petition lacked the same information. The Citizen Petition Denial Letter, which came five days after the denial of Teva's Plan B One-Step application, was clearly prompted by the Secretary's action despite the FDA's fanciful effort to make it appear that it undertook an independent review of the Citizen Petition. *See Tummino v. Hamburg*, 2013 WL 1348656 at *26.

On April 5, 2013, I issued an order directing the defendants—the Commissioner of Food and Drugs and the Secretary of Health and Human Services—to grant the Citizen Petition filed by the plaintiffs and make levonorgestrel-based emergency contraceptives available over-the-counter and without point-of-sale or age restrictions. I did so because the Secretary's action was politically motivated, scientifically unjustified, and contrary to agency precedent, and because it could not provide a basis to sustain the denial of the Citizen Petition.[1] I did not order the defendants to make Plan B One-Step—the widely known brand name emergency contraceptive—available. Teva had not appealed from the FDA's denial of its application, and, although it sought to intervene in this lawsuit, its intervention was not for the purpose of obtaining any relief related to its ability to market Plan B One-Step.

[1] The defendants do not suggest that they have any reasonable possibility of success in challenging this finding on appeal.

Plan B One-Step aside, the effect of my decision was to make levonorgestrel-based emergency contraceptives available without a prescription and without any point-of-sale or age restrictions. The only practical difference between my decision and the decision of the FDA that the Secretary reversed was that the FDA's decision was arguably directed towards the one-pill version of the drug, and my decision applied to both versions. Nevertheless, responding to far-fetched concerns ultimately voiced in response to the prospect of making the two-pill version available without a prescription, I advised the FDA that if it actually believed there was a significant difference between the one- and two-pill products, it was free to limit the relief on the Citizen Petition to the one-pill product. *Tummino v. Hamburg*, 2013 WL 1348656 at *31.

With this concession to the FDA's concerns, my decision was entirely consistent with the initial decision of the FDA. I adopted and completely agreed with Commissioner Hamburg's conclusion that "there is adequate and reasonable, well-supported, and science-based evidence that Plan B One-Step is safe and effective and should be approved for nonprescription use for all females of child-bearing potential"—a conclusion that she reached after she had "reviewed and thoughtfully considered the data, clinical information, and analysis provided by" the FDA's Center for Drug Evaluation and Research. Statement from FDA Commissioner Margaret Hamburg, M.D., on Plan B One-Step (Dec. 7, 2011). Notwithstanding my deference to the Commissioner and the scientists at the FDA, the defendants have filed a notice of appeal and a motion to stay my decision as they continue their administrative agency filibuster through the appellate process.

I pause here before proceeding to a discussion of the merits of the motion to comment on the defendants' analysis of the manner in which drug approval applications should be made. Thus, they tell me that "[a] drug approval decision involves scientific judgments as to whether

statutory and regulatory factors are met that warrant deference to those charged with the statutory responsibility to make those decisions. The agency alone has the necessary information and scientific expertise to assess the data and information required to make a determination that a drug is safe and effective." Defs.' Br. at 10. This salutary principle was flagrantly violated by Secretary Sebelius, who completely lacks the "necessary information and scientific expertise to assess the data and information required to make a determination that a drug is safe and effective," and whose role in the process has been circumscribed by Congress as well as by the delegation to the Commissioner of any authority that the Secretary may have—a clear recognition by Congress and the Secretary of her lack of competence in this area. *See Tummino v. Hamburg*, 2013 WL 1348656 at *21. Yet, in something out of an alternate reality, the defendants seek a stay to pursue an appeal that would vindicate the Secretary's disregard of the very principle they advocate.

DISCUSSION

There are four factors to be considered before granting a stay pending appeal: (1) whether a party will suffer irreparable injury if a stay is issued, (2) whether the movant will suffer irreparable injury absent a stay, (3) whether the movant has demonstrated a substantial possibility, although less than a likelihood, of success on appeal, and (4) the public interests that may be affected. *Hirschfeld v. Bd. of Elections*, 984 F.2d 35, 39 (2d Cir. 1993); *see also In re World Trade Ctr. Disaster Site Litig.*, 503 F.3d 167, 170-71 (2d Cir. 2007). In *Mohammed v. Reno*, 309 F.3d 95 (2d Cir. 2002), the Second Circuit surveyed how different courts have analyzed the prospect of success necessary for issuing a stay, ultimately agreeing with the District of Columbia Circuit's approach, whereby "[t]he necessary 'level' or 'degree' of possibility of success will vary according to the Court's assessment of the other [stay] factors."

Id. at 101 (quoting *Washington Metro. Area Transit Comm'n v. Holiday Tours, Inc.*, 559 F.2d 841, 843 (D.C. Cir. 1977)). The court observed: "[t]he probability of success that must be demonstrated is inversely proportional to the amount of irreparable injury plaintiff will suffer absent the stay. Simply stated, more of one excuses less of the other." *Mohammed*, 309 F.3d at 101; *see also Citigroup Global Mkts., Inc. v. VCG Special Opportunities Master Fund, Ltd.*, 598 F.3d 30, 36-38 & n.8 (2d Cir. 2010). Against this backdrop, I turn to a discussion of the relevant factors.

Irreparable Injury to the Plaintiffs

The defendants' argument that the plaintiffs will not suffer any harm if a stay is granted is based solely on an agreement they reached with Teva the day before they filed their notice of appeal. This argument necessitates a discussion of the agreement and how it came to be made. On March 9, 2012, three months after the Secretary overruled the FDA and directed the denial of Teva's application to make Plan B One-Step available over-the-counter without a prescription to all women, Teva filed a letter with the FDA seeking to make Plan B One-Step available for sale to women 15 years of age and over without a prescription and to eliminate the sale of Plan B One-Step by prescription for women under 15 years of age. Under this proposal, the drug would be stocked on the shelves of any retail establishment with an on-site pharmacy, and customers would be required to prove their age by providing photo identification to the cashier of the retail establishment as opposed to the pharmacist.

Teva and the FDA exchanged correspondence regarding this proposal through June 2012. After an eight-month hiatus, they resumed communication in March 2013, shortly after I indicated my intention to rule on the plaintiffs' Citizen Petition by the end of March—a decision which the defendants had to have known from oral argument would strike down the order of the

Secretary and the FDA's action which was dictated by it. My decision was filed on April 5, 2013. Teva's application was approved on April 30, 2013, the day before defendants in this case filed their notice of appeal. The FDA has provided for no reason for the delay in ruling on Teva's application. Indeed, as I observed at oral argument, the approval—when it finally came—was intended to provide a sugarcoating for the FDA's appeal. May 7, 2013 Hr'g Tr. 28:2-5.

Nevertheless, there was something in it for Teva as well. The benefits the proposal would confer on Teva were not insignificant. Because, as the Assistant United States Attorney observed, 99% of Plan B One-Step consumers are aged 15 and above, Teva would lose next to nothing in the way of revenue by limiting sales to those women. May 7, 2013 Hr'g Tr. 68:7-11. On the other hand, Teva's proposal would enable it to have its product, and its product alone, displayed on the shelves in the family planning area of stores with an on-site pharmacy. Thus, a consumer looking for an emergency contraceptive would only find Plan B One-Step on the shelves, and if she came in after the pharmacy counter was closed, her only option would be Plan B One-Step. If she were under the age of 15, she would have no option, because she could only obtain levonorgestrel-based emergency contraceptives with a prescription.

Moreover, because the FDA claimed that one of the studies conducted by Teva—the so-called "actual use" study—was essential to the approval of Teva's proposal, Teva enjoys three years of marketing exclusivity to the 15 and 16 year old consumers. The pharmaceutical companies that sell "brand X" versions of Plan B One-Step as well as the two-pill package of the drug could not display their products on the shelf because the old marketing regime remains in effect for them, and their products can only be sold from behind the pharmacy counter. Anyone

under the age of 17 needs a prescription to obtain these products, and anyone over the age of 17 can only obtain them from the pharmacy by showing proof-of-age identification.

While this proposal was a boon to Teva, it did little to eliminate the practical obstructions in obtaining emergency contraception to women of child-bearing age whether over or under age 15. On the contrary, Teva will use its privileged marketing status and exclusivity to increase the cost of the drug. The price of Plan B One-Step under the new marketing regime is expected to be $60, significantly more than the one- or two-pill generic version, and could conceivably go higher, if only to accommodate the more expensive packing, age-verification tags, and anti-theft technology that the new marketing arrangement would require. May 7, 2013 Hr'g Tr. 29:9-15. The cost of all emergency contraception, particularly Plan B One-Step, which is the most expensive, is already an impediment to access for many women and adolescents.

Nevertheless, the Secretary of Health and Human Services and the Commissioner of Food and Drugs argue that a stay of my order to make levonorgestrel-based emergency contraceptives available without a prescription and without point-of-sale and age restrictions "will not harm plaintiffs." Defs.' Br. at 11. This argument is based on the premise that the plaintiffs "are all over age 15 and therefore will soon be able to obtain at least one emergency contraceptive containing levonorgestrel . . . without a prescription at retail establishments that have a pharmacy counter." *Id.* Thus, the order that I entered and they seek to appeal "is not required to afford relief to any of the plaintiffs. They can purchase the product whenever the store is open (regardless of whether the pharmacy is open) by showing proof of age." *Id.*

Passing over the fact that the complaint alleges that one of the plaintiffs is suing on behalf of her two daughters, one of whom was 12 years old on May 23, 2012 (when the second amended supplemental complaint was filed), the defendants' argument ignores (1) the fact that

"showing proof of age," which means government-issued photo identification, constitutes a substantial impediment to obtaining emergency contraception, particularly for young women of reproductive age, and (2) that emergency contraception can only be obtained at retail establishments with on-site pharmacies. Moreover, while there are some retail establishments that are open for longer hours than their pharmacy counters, the unjustifiable point-of-sale restrictions left in place under the Teva-FDA agreement will continue to present barriers to all women. Many women do not live near a store with an on-site pharmacy, and even when the drugstore or comparable facility has an on-site pharmacy, the difference between the hours of the pharmacy and the store itself is often significant. Indeed, a research letter published in the journal of the American Medical Association found that "of the 943 pharmacies called" in a survey of emergency contraceptive availability in five geographically diverse cities, "only 4.7% were open 24 hours." Tracey A. Wilkinson et al., *Research Letter: Access to Emergency Contraception for Adolescents*, 307 J. Am. Med. Ass'n 362 (January 25, 2012).

Significantly, a study conducted by the Brennan Center for the purpose of showing the extent to which photo identification requirements throw roadblocks in the way of voters found that African-American citizens disproportionately lack photo identification. Specifically, "[t]wenty-five percent of African-American voting-age citizens have no current government-issued photo ID, compared to eight percent of white voting-age citizens." Brennan Center for Justice, *Citizens Without Proof* 3 (Nov. 2006), *available at* http://www.brennancenter.org/analysis/citizens-without-proof. Using 2000 census figures, the Brennan Center concluded that "this amounts to more than 5.5 million adult African-American citizens without photo identification." *Id.* Similarly, "[c]itizens earning less than $35,000 per year are more than twice as likely to lack current government-issued photo identification as those earning more than

$35,000. Indeed, the survey indicates that at least 15 percent of voting-age American citizens earning less than $35,000 per year do not have a valid government-issued photo ID." *Id.* Indeed, proposed findings of fact submitted by the Department of Justice in *South Carolina v. Holder*, No. 12-cv-203 (D.D.C.), are consistent with the Brennan Center study. One of those proposed findings is that "[m]inority voters in [South Carolina] are disproportionately less likely than white voters to possess any of the currently available, acceptable forms of [photographic voter identification] . . . . This conclusion holds true for black voters, Native American voters, and Hispanic voters, all of whom are significantly less likely than white voters to possess an allowable [photograph voter identification] . . . . These disparities are statistically significant."[2] United States' Proposed Findings of Fact and Conclusions of Law at 8, *South Carolina v. Holder*, No. 12-cv-203 (D.D.C.).

These statistics do not necessarily correlate with women of reproductive age. Nevertheless, they indicate the disproportionate burden that the Teva-FDA agreement places on African-American and poor adults over age 18. Moreover, it can reasonably be assumed that the proportion of women between 15 and 18 who lack government-issued photo identification is much higher, with a similar disparate impact on African-Americans and the poor. Nor does the nature of the age identification required under Teva's proposal make any concession to the difficulties they face. Thus, in response to a question posed by the FDA, Teva responded that "[t]he age verification system is based on federal and state guidelines for the sale of tobacco and alcohol and as such requires a government-issued photo ID (including driver's license, military card, immigration card, or passport) with date of birth." Letter from Valerie M. Mulligan, Senior

[2] The Brennan Center survey found that 16% of Hispanic voting age citizens have no current photo identification, but observed that the results did not achieve statistical significance due to a low sample size. The Department of Justice, which characterized its statistics as more robust, seems to confirm the validity of the Brennan Center's findings with respect to Hispanics.

Dir. of Reg. Affairs, Teva Women's Health, to Andrea Leonard-Segal, Center for Drug Evaluation and Research, FDA at 2 (June 27, 2012).[3] Teva also observed that "a school-issued ID and birth certificate would not be considered acceptable age-verification." And, "for consumers age 15, there are some states that issue a driver's permit at age 15, or a consumer may use one of the other types of ID listed above, *if available*." *Id.* (emphasis added).

Moreover, the Teva-FDA agreement does nothing to relieve the burden on younger adolescents who still require a prescription from a physician in order to obtain an emergency contraceptive. Indeed, because the Teva-FDA agreement provides that Teva will no longer market Plan B One-Step as a prescription product, younger adolescents receive no benefit from the new marketing agreement. Instead, the requirement of a prescription only adds the additional cost of a doctor's visit and delay to obtaining a time-sensitive emergency contraceptive that is more effective the sooner it is taken after unprotected intercourse. As the label on the Plan B One-Step box advises the consumer, the pill should be taken "as soon as possible . . . after unprotected sex." I do not dwell on this aspect of the prejudice suffered by the population of the youngest adolescents, although it should not be ignored, because the number of these adolescents who actually use levonorgestrel-based emergency contraceptives is miniscule, and they have been invoked in the debate over access to these contraceptives mostly as a red herring to justify the continued burdens suffered by older women who seek access to the drug.

Irreparable Injury to the Defendants and the Public Interest

The defendants argue that they "and the public interest" will suffer irreparable harm absent a stay for a number of reasons. Thus, they argue that the FDA and the public will be

[3] I recognize that I am quoting from a letter that has been filed under seal and the contents of which Teva objects to being made public. The instance which I have quoted simply cannot be described as the equivalent of a confidential trade secret or other protected information that would justify keeping it a secret. Indeed, as I understand the position of the FDA, it retains the discretion to release information from Teva's letters now that its application has been granted. Letter from the United States Attorney at 1 (May 6, 2013).

irreparably and immediately harmed "if a drug product that purported to be 'FDA approved' were approved instead at the direction of a court." Defs.' Br. at 12. This is so because, they suggest, "[t]he public properly relies upon FDA classification of drugs as non-prescription as a reflection of the agency's judgment regarding the safety and proper use of a drug without a doctor's prescription. Thus, the public interest will not be served by reclassification of drugs as non-prescription without agency approval." *Id.* at 12-13. This argument ignores the fact that the FDA found that the drug was safe and could be used properly without a doctor's prescription, and was prepared to make it available over-the-counter for all ages. As Commissioner Hamburg observed, "there is adequate and reasonable, well-supported, and science-based evidence that Plan B One-Step is safe and effective and should be approved for nonprescription use for all females of child-bearing potential." Statement from FDA Commissioner Margaret Hamburg, M.D., on Plan B One-Step (Dec. 7, 2011). Thus, if a stay is denied, the public can have confidence that the FDA's judgment is being vindicated, and if a stay is granted, it will allow the bad-faith, politically motivated decision of Secretary Sebelius, who lacks any medical or scientific expertise, to prevail—thus justifiably undermining the public's confidence in the drug approval process.

Nor is there any merit to the related argument that a stay will "prevent public uncertainty regarding the status of the drugs at issue here pending the government's appeal to the Second Circuit." Defs.' Br. at 13. This silly argument ignores the fact it is the government's appeal from the order that sustained the judgment of the Commissioner of the FDA that is the cause of any uncertainty, and that that appeal is taken solely to vindicate the improper conduct of the Secretary and possibly for the purpose of further delaying greater access to emergency

contraceptives for purely political reasons. Whether my order is stayed or not will not resolve any uncertainty.

The defendants also argue that "if the status of these drugs is changed and later reversed, it can lead to situations in which women mistakenly believe that they can obtain the drug without a prescription or at certain locations where it used to be available, but is no longer." Defs.' Br. at 13. This argument assumes that defendants have a likelihood of success on the merits, an issue that I will shortly address, and is largely an insult to the intelligence of women. If women can no longer obtain Plan B without a prescription at certain locations, they will go to locations where it is available. On the other hand, if a stay is granted, the prejudice to those who need ready access to emergency contraceptives is a certainty, and is likely to continue until the resolution of the appeal—a period of time which is difficult to predict.

Moreover, this argument comes with ill grace from the defendants, who have added significant confusion by putting in place a convoluted triple-tiered marketing scheme that will only increase the confusion that already prevents women from obtaining timely access to emergency contraceptives. Specifically, women and retailers across the country will be forced to operate under the following set of nonsensical rules: (1) women 15 years of age or older with adequate proof of age will be permitted to purchase Plan B One-Step, which will only be available on the shelves in stores with on-site pharmacies; (2) other levonorgestrel-based products will remain behind the counter, but will be available without a prescription to women over 17 years of age who have government issued proof of age; and, (3) women who lack adequate proof of age or are under the age of 15 will not have access to Plan B One-Step and must obtain a prescription for another levonorgestrel-based contraceptive product. The confusion caused by this system, the only purpose of which is to sugarcoat the defendants'

appeal, is much greater than any potential confusion that could result from simply returning a product to prescription status.

The defendants' last argument is that the government interest in conferring marketing exclusivity will be irreparably harmed absent a stay. I do not question the validity of the policies underlying the statutes and regulations conferring marketing exclusivity on pharmaceutical companies that perform needed research to make drugs available and obtain approval to market drugs as a result. Nevertheless, at the time of my decision there was no issue of market exclusivity, because Teva's previous applications to expand access to Plan B One-Step had been denied, and it had not appealed. Indeed, for this reason, the prejudice that the defendants claim is the *implication* in my decision "that FDA cannot grant Teva marketing exclusivity for a change for [Plan B One-Step] from prescription to [over-the-counter] simply because FDA issued a complete response letter to Teva in December 2011 and Teva chose not to file a petition for review to the court of appeals." Defs.' Br. at 15. Their argument continues that "[t]his implication ignored the prospect that, instead of appealing, Teva could file an amended [supplemental application], which FDA could approve, leading to a grant of exclusivity." *Id.* It is not my understanding that any implication that could conceivably be drawn from an opinion provides a basis for an appeal, much less for a stay pending appeal.

Moreover, if I was operating in ignorance of the fact that Teva was negotiating a sweetheart agreement with the FDA, it was because nothing happened in this regard from December 2011 until April 30, 2013, 25 days after I issued my opinion in this case. Indeed, it would not have been unreasonable for me to assume that after 16 months of silence, the verdict of the quiescent years—to borrow a phrase from Brainerd Currie—was that nothing happened. Nevertheless, I acknowledge that I ordered the Citizen Petition be granted in part because it was

my view that the plaintiffs were entitled to the relief they sought even without the actual use study paid for by Teva. Indeed, the 2003 FDA advisory committee formed to consider the first application for over-the-counter access to levonorgestrel-based emergency contraceptives voted by the most overwhelming of margins to approve it, without the benefit of the actual use study that Teva submitted with its more recent application, and it was only the political interference by the Bush White House that prevented their recommendation from being adopted. *See Tummino v. Torti*, 603 F. Supp. 2d 519, 528 (E.D.N.Y. 2009). If Teva could somehow benefit from the relief sought by the Citizen Petition, it was simply because the relief it sought from the FDA overlapped to a degree with the Citizen Petition.

Defendants' Likelihood of Success on the Merits

The defendants offer two arguments in support of their claim that they have "a substantial likelihood of success on appeal." Defs.' Br. at 5. The first argument is that I was without subject matter jurisdiction to review the denial of Teva's petition. This argument is frivolous. I repeatedly recognized in my opinion, as the defendants acknowledged in their memorandum in support of their motion for a stay, that I did not have the authority to review the denial of Teva's petition for the purpose of granting relief. Defs.' Br. at 7. Nor did I direct the defendants to grant Teva's petition. I need not burden this opinion with a further discussion of this claim, because it is belied by what has actually happened since my opinion. Specifically, Teva is not making any effort to take advantage of my decision. Instead, it has entered into an agreement with the FDA, which I previously described. Since Teva has acquiesced in the denial of its petition, and entered into an agreement designed to "address the Secretary's stated concerns," there is nothing for the Court of Appeals to review, even if my decision had affected Teva's petition. Letter from Valerie M. Mulligan, Senior Dir. of Reg. Affairs, Teva Women's Health, to

Andrea Leonard-Segal, Center for Drug Evaluation and Research, FDA at 3 (Mar. 9, 2012). Indeed, this issue could be said to be moot.

The defendants' next argument in support of their claim that they have a substantial likelihood of success on appeal is that I exceeded my authority in ordering a change of Plan B for prescription to over-the-counter instead of remanding to the agency. Specifically, the defendants argue that "[r]ather than issuing a directive to the agency as to what specific action to take, the Court should have remanded to the agency for compliance with its legal ruling." Defs.' Br. at 9. Quoting from a decision of the Supreme Court, they argue that "the proper course, *except in rare circumstances*, is to remand to the agency for additional investigation or explanation. The reviewing court is not *generally* empowered to conduct a *de novo* inquiry into the matter being reviewed and to reach its own conclusions based on such an inquiry." *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985) (emphases added).

The defendants' own admission that they could not continue to reach the same decision on remand after remand and claim that the only remedy was yet another remand clearly establishes that the question is not whether I have authority to grant relief. *See* May 7, 2013 Hr'g Tr. 91:22-92:6. So too does a careful study of the language of the Supreme Court decision on which they rely, and which recognizes that there are "rare circumstances" in which remand is not necessary. This case presents the kind of "rare circumstances" where a remand to the agency is not only unnecessary but would constitute an abuse of discretion. First, the FDA is not the problem. The cause of the rejection of over-the-counter sale of levonorgestrel-based emergency contraceptives was the Secretary of Health and Human Services. She has not changed her position. *Id.* 17:14-20. A remand would thus be futile.

More significantly, I have been there and done that. In my 2009 opinion, after concluding that the administrative agency process was corrupted by political interference, I declined the plaintiffs' request to avoid a remand and simply direct that the FDA award them the relief that they sought. I did so for two reasons. First, it was my view that a decision on whether Plan B "may be used safely without a prescription by children as young as 11 or 12, is best left to the expertise of the FDA, to which Congress has entrusted this responsibility; it should not be made by a federal district court judge." *Tummino v. Torti*, 603 F. Supp. 2d at 549. Second, a new FDA Commissioner, Deputy Commissioner, and President had come into office since the agency's decision on Plan B had been made, who I thought could be "trusted to conduct a fair assessment of the scientific evidence." *Id.* Neither of these grounds is applicable here.

On remand, defendants engaged in the same bad faith that resulted in my initial remand. They delayed the decision for three years and, ultimately, improper political influence prevented the FDA from granting the petition. Nor do they claim a reasonable probability of success on appeal in challenging my analysis of their flagrant misconduct. Indeed, I traced the numerous departures from agency policy and defects in the proceedings for yet a second time. *Tummino v. Hamburg*, 2013 WL 1348656 at *6-19. Significantly, defendants do not take any issue with any of my substantive conclusions. Instead, they seek another remand, without any assurance that the result would be any different. On the contrary, the defendants assert that, even if the Secretary changed her mind and the FDA agreed that the Citizen Petition contained sufficient data to support an over-the-counter switch, the FDA would be obligated to conduct what could be described as a national referendum: "[A] rule making proceeding [in] which the public and all stakeholders would have an opportunity to participate and share their views including Teva, including plaintiffs, including the petitioners, including anybody else who has an interest in the

issue would be able to submit their views." May 7, 2013 Hr'g Tr. 22:13-24. I need not here deal with the argument that such a rulemaking procedure would be required in the ordinary case.[4] As I noted in my earlier opinion:

> [T]he bad faith that has permeated consideration of the Citizen Petition, not to speak of the Plan B sponsor's applications, should rule out such relief here. More than twelve years have passed since the Citizen Petition was filed and eight years since this lawsuit commenced. The FDA has engaged in intolerable delays in processing the petition. Indeed, it could accurately be described as an administrative agency filibuster. Moreover, one of the devices the FDA has employed to stall proceedings was to seek public comment on whether or not it needed to engage in rulemaking in order to adopt an age-restricted marketing regime. After eating up eleven months, 47,000 public comments, and hundreds of thousands, if not millions, of dollars, it decided that it did not need rulemaking after all. The plaintiffs should not be forced to endure, nor should the agency's misconduct be rewarded by, an exercise that permits the FDA to engage in further delay and obstruction.

Tummino v. Hamburg, 2013 WL 1348656 at *33.

CONCLUSION

The motion for a stay pending the appeal is denied. Indeed, in my view, the defendants' appeal is frivolous and is taken for the purpose of delay. Nevertheless, as a courtesy to the Court of Appeals, and to enable it to schedule the motion in the ordinary course, I grant a stay pending the hearing or submission of the defendants' motion for a stay in the Court of Appeals on the condition that the motion for a stay be filed by noon on May 13, 2013.

SO ORDERED.

Brooklyn, New York
May 10, 2013

Edward R. Korman

Edward R. Korman
Senior United States District Judge

[4] I discuss this issue in some detail in my April 5th opinion. *Tummino v. Hamburg*, 2013 WL 1348656 at *32-33. One of the points I made was that the last time I remanded the Citizen Petition, it was with instructions to lower the age for non-prescription sale from 18 to 17. The agency accomplished this without rulemaking by inviting Teva to submit a tailored supplemental application for this change. *Id.* at *10.